

## **REMARKS**

Claims 1-4, 12, 18, 21, 23 and 24 are currently pending. Claims 1-4, 5-12, 13-21, and 23- 25 are amended and are also under consideration.

The Examiner has rejected claims 1-4, 21, 23 and 24 based on prior art cited **IN THE FEBRUARY 5, 2003 OFFICE ACTION**. The Examiner states in her September 17, 2003 Office Action that ***"The pages and line numbers pointed to fail to provide support for the limitations made in the amendment dated May 22, 2003."***

### Office Action of February 5, 2003

Claims 1-4 and 21-24 were rejected under 35 U.S.C. 102(e) as being anticipated by Armstrong et al., U.S. 6,099,469). The Action states:

*"As stated previously, Armstrong et al, meet the limitations of the steps set forth in the generic claims and the apparatus of Armstrong et al meets all of the limitations of the generic apparatus of the instant invention.*

*As set forth, Armstrong et al disclose a disease specific algorithm for use in a computer assisted method that analyzes what clinical tests should be performed. The particular disease state of Armstrong et al is acute myocardial infarction. A first test is performed on the sample, then, based upon result comparisons with preset guidelines, a second test is run. In the conditions set forth in column 3, line 52- column 4, line 12, it is clear that the invention of Armstrong provides means for omitting the execution of unnecessary assays*

*while ensuring that all necessary combinations of laboratory tests are covered. Furthermore, the reflex algorithm of the invention automatically selects appropriate markers for a given clinical situation such that human decision-making is eliminated.*

In Response, applicant disagrees. Armstrong et al.'s reflex algorithm is used to monitor a number of biochemical markers, which change in a time-sensitive manner during a myocardial infarction episode, for example creatinine kinase, myoglobin and troponin. These time dependent changes in the specific biomarkers are monitored by a technician in order to determine the stage at which the myocardial infarction is being monitored. And, sometimes, this requires that the same biomarker test be run repeatedly every four hours in order to follow the progression of the myocardial infarct. In other words, it is the technician who decides as to whether to repeat any testing. The reflex algorithm merely indicates how a measurement for a biomarker compares with a predetermined level.

In contrast, in the present invention, first step in the algorithmic clinical testing is to determine which of the tests ordered by a physician are truly essential to diagnose a specific suspected disease. After this, the algorithm executes the necessary tests in a sequential manner, to obtain an accurate diagnosis. The present system DOES NOT PERMIT A TECHNICIAN OR OPERATOR TO TAMPER WITH THE ALGORITHM. The objective in the present invention is to provide a cost-effective, rapid, efficient system that can be used in the diagnosis of many diseases in which the markers being measured

have stable values. The system is capable of carrying out intelligent programming to effectuate diagnosis and does not need the technician to make the decisions as is the case in Armstrong et al. The section cited in the rejection does not cover the above distinguishing element, and therefore, as a matter of fact and law, the above rejection must be withdrawn. This is because the Federal Circuit has held that:

"It is axiomatic that for prior art to anticipate under 102 it has to meet every element of the claimed invention". Hybritech Inc. v. Monoclonal Antibodies Inc. 802 F.2d 1367, 231 USPQ 81 (Fed. Cir. 1986). "For a prior art reference to anticipate in terms of 35 U.S.C. Section 102, every element of the claimed invention must be identically shown in a single reference - - - These elements must be arranged as in the claim under review, - - -." In re Bond, 910 F.2d 831, 15 USPQ 1566 (Fed. Cir. 1990)."

Therefore, as a matter of law and fact, the rejection of claims 1-4 and 21-24 based on Armstrong et al. must be withdrawn.

Claims 1-4 and 21-24 were rejected under 35 U.S.C. 102(e) as being anticipated by Carlson et al. (U.S. 6,140,065). The Action States:

*Carlson et al (US 6,140,065) disclose computer-assisted methods for diagnosing a disease state based upon a reflex algorithm. Applicant argues that the amendments to the claims make them allowable over Carlson. However, as stated above in reference to Armstrong et al, the claims state that tests are run on a sub-group showing abnormality, thereby not allowing UNNECESSARY*

*clinical tests to be carried out in duplicate or to be ordered by an outside operator. However, this does not imply that the tests still cannot be run or that an operator is not utilized when a NECESSARY test is indicated. The rejection is maintained.*

In response, applicants disagree. What is the basis for the Examiner to conclude : *"However, this does not imply that the tests still cannot be run or that an operator is not utilized when a NECESSARY test is indicated. The rejection is maintained?"* Obviously, the Examiner is providing her own opinion, and speculating, something that the MPEP does not permit. She should provide objective support for her opinion.

Importantly, Carlson does not have the essential element of the algorithm being tamper proof from an operator, and the algorithm selecting at the first stage, only tests relevant to the diagnosis of a specific suspected disease. The legal standard for a section 102 rejection, requiring each and every element to be present in the cited reference, as discussed above, applies to this rejection as well. Therefore the rejection based on Carlson must be withdrawn as a matter of law and fact.

Claims 1-4, 18 and 21-24 were rejected under 35 U.S.C. 102(b) as being anticipated by Adlassnig et al. (Artificial Intelligence in Medicine, (1995) Vol 7. pages 1-24). The Action states:

*Adlassnig et al disclose the HEPAEXPERT –1 computer algorithm that is useful in obtaining a diagnosis of HBV infection. As shown in figure 2 and 3 typical serology for a variety of HBV infection are used for identifying which*

*clinical tests to run. Rules are written in to computer memory for normal and typical scenarios of HBV infection and the computer goes through a variety of test combinations to establish a diagnosis. The programmed computers of Adlassnig et al meet all of the limitations of the instant claims.*

In response, applicant disagrees because Adlassnig does not meet the following limitation of the instant claims: the present algorithm is tamper proof from an operator, and the algorithms selects at the first stage, only tests relevant to the diagnosis of a specific suspected disease, irrespective of the tests ordered by a physician.

This limitation has important implications in making the health system cost effective. This is because physicians usually order unnecessary tests, sometimes unrelated to the diagnosis of a suspected disease, usually under the guise of "routine health check-up". The algorithms developed in present invention prevent the unnecessary tests and stop an operator from overriding the algorithm.

As discussed by applicant's attorney during the telephone interview, none of the cited references has the limitation that an external operator or technician cannot add tests that are deemed unnecessary. This is because the algorithm has a control system that checks against unnecessary tests right at the first stage of the invention. Applicant's invention is much needed and will make an impact on the cost of health care.

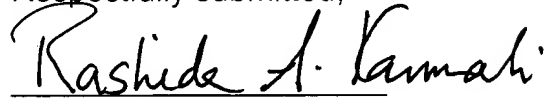
Examiners Clow and Woodward agreed during the interview that this is a distinguishing feature of the present invention, that overcomes all of the above

cited art. Therefore, there is no basis for any of the rejections made in the September 17, 2003 Action. Pending claims 1-4, 12, 18, 21, 23 and 24 should be allowed.

Applicant has made a diligent effort to place this application in condition for allowance and notice to the effect that claims 1-4, 12, 18, 21, 23, and 24 are in condition for allowance is earnestly solicited. If for any reason however, the Examiner should deem that this application is not in condition for allowance, the Examiner is respectfully requested to telephone the undersigned attorney at the number listed below to resolve any outstanding issues prior to issuing a further Office Action.

In addition, upon allowance of these generic claims, Applicant requests that claims 5-11, 13-20 and 25 be reinstated as being drawn to non-elected species, which was the condition of the Restriction Requirement.

Respectfully submitted,



Rashida A. Karmali, Esq.

Reg. No. 43,705

Attorney for Applicants

99 Wall Street, 13<sup>th</sup> floor

New York, New York 10005

Tel: 212-651-9653

Fax: 212-651-9654

Date: February 3, 2004

**CERTIFICATE OF EXPRESS MAILING**

I hereby certify that this correspondence is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" Service under 37 C.F.R. 1.10 on February 3, 2004, Express Mail Mailing Label No. ER 168668475 US--addressed to: Commissioner for Patents, P.O.Box 1450, Alexandria, VA 22313-1450.

Rashida A. Karmali  
Attorney for Applicants

Rashida A. Karmali

Signature

2/3/2004

Date of Signature